

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA**

SHENIKA J. HOUSTON,

Plaintiff,

v.

**BAYER HEALTHCARE
PHARMACEUTICALS INC.,**

Defendant.

CASE No. 2:14-cv-00035-WMA

BAYER HEALTHCARE PHARMACEUTICAL INC.'S ORIGINAL ANSWER

Defendant Bayer HealthCare Pharmaceuticals Inc. ("BHCP"), by and through its undersigned counsel, hereby answers Plaintiff's Complaint (the "Complaint"). BHCP specifically denies each and every allegation of the Complaint not otherwise expressly admitted, qualified, or denied in this Answer.

FIRST RESPONSE TO "PARTIES AND CITIZENSHIP"

1. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 of the Complaint.

2. The allegations contained in Paragraph 2 are denied as stated. BHCP admits that it is a Delaware corporation with its principal place of business located at 100 Bayer Boulevard, Whippany, New Jersey 07981.

3. The allegations contained in Paragraph 3 are denied as stated. BHCP admits that Bayer HealthCare Pharmaceuticals Inc., formerly known as Berlex, Inc., formerly known as Berlex Laboratories, Inc., a Delaware corporation, is wholly owned by Schering Berlin Inc., a Delaware corporation, which is wholly owned by Bayer HealthCare LLC.

4. The allegations contained in Paragraph 4 are denied as stated. BHCP admits that Bayer HealthCare Pharmaceuticals Inc., formerly known as Berlex, Inc., formerly known as Berlex Laboratories Inc., a Delaware corporation, is wholly owned by Schering Berlin Inc., a Delaware corporation, which is wholly owned by Bayer HealthCare LLC.

5. BHCP admits that it is the holder of the approved “NDA” for the contraceptive system Mirena[®].

6. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, advertised, promoted, marketed, sold, and distributed Mirena[®] as an intrauterine contraceptive system (“IUS”). Due to the vagueness, ambiguity, and potential redundancy of any remaining allegations in Paragraph 6, BHCP is without knowledge or information sufficient to form a belief as to the truth of those.

7. BHCP admits that, at certain times not specifically set forth in the Complaint, it sold Mirena[®] in the United States, including in the State of Alabama. BHCP denies the remaining allegations in Paragraph 7 of the Complaint.

8. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, marketed, distributed, and/or sold Mirena[®] in the United States. Due to the vagueness, ambiguity, and potential redundancy of any remaining allegations in Paragraph 8, BHCP is without knowledge or information sufficient to form a belief as to the truth of those. BHCP denies the remaining allegations in Paragraph 8 of the Complaint.

FIRST RESPONSE TO “JURISDICTION AND VENUE”

9. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint.

10. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint.

11. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint.

FIRST RESPONSE TO “FACTS”

12. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 11 of the Complaint.

13. BHCP admits that Mirena[®] is an IUS made of soft, flexible plastic, which is put in place by a healthcare provider during an office visit. BHCP also admits that Mirena[®] contains 52 mg of levonorgestrel, which is released at a rate of approximately 20 mcg/day. This rate decreases progressively to half that value after 5 years.

14. BHCP admits that the FDA approved Berlex Laboratories, Inc.’s new drug application in December 2000.

15. BHCP admits that in 2009 the FDA approved Mirena[®] as a treatment indicated for heavy menstrual bleeding.

16. BHCP admits that Mirena[®] has been chosen by over 15 million women worldwide, 2 million in the United States. BHCP denies any remaining allegations in Paragraph 17 of the Complaint.

17. BHCP admits that Mirena[®] is a levonorgestrel-releasing intrauterine contraceptive that delivers small amounts of hormone directly to the uterus.

18. BHCP answers that, to the extent the second sentence of Paragraph 18 of the Complaint purports to quote from the FDA-approved Patient Information Booklet, which

document speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language and content of the document, BHCP denies those allegations.

19. BHCP admits that the allegations in Paragraph 19 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

20. BHCP admits that the allegations in Paragraph 20 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

21. BHCP admits that the allegations in Paragraph 21 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

22. BHCP admits that the allegations in Paragraph 22 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

23. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 23 of the Complaint.

24. BHCP admits that the allegations in Paragraph 24 purport to summarize or interpret from the FDA-approved Physician Prescribing Information, which document, being in

writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

25. Paragraph 25 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations of Paragraph 25 as written. To the extent the allegations in Paragraph 25 purport to summarize from the FDA-approved Physician Prescribing Information, this document, being in writing, speaks for itself.

26. Paragraph 26 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP admits that the allegations in Paragraph 26 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

27. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 27 of the Complaint.

28. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 28 of the Complaint.

29. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of the Complaint.

30. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 of the Complaint.

31. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 of the Complaint.

32. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 32 of the Complaint.

33. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 33 of the Complaint.

34. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 34 of the Complaint.

35. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 35 of the Complaint.

36. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 36 of the Complaint.

37. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 37 of the Complaint.

38. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 38 of the Complaint.

39. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 39 of the Complaint. Therefore, BHCP denies these allegations.

40. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 40 of the Complaint.

41. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 41 of the Complaint.

42. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42 of the Complaint.

43. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 43 of the Complaint.

44. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 of the Complaint.

45. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 45 of the Complaint.

46. To the extent the allegations in Paragraph 46 apply to Mirena[®], BHP denies the allegations. To the extent the allegations in Paragraph 46 apply to a product other than Mirena[®], BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 46 of the Complaint.

47. To the extent the allegations in Paragraph 47 apply to Mirena[®], BHP denies the allegations. To the extent the allegations in Paragraph 47 apply to a product other than Mirena[®], BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 of the Complaint.

48. BHCP denies the allegations in Paragraph 48 of the Complaint.

49. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 49 of the Complaint.

50. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 50 of the Complaint.

51. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 51 of the Complaint.

52. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 of the Complaint.

53. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 53 of the Complaint.

54. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 54 of the Complaint.

55. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 55 of the Complaint.

56. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 56 of the Complaint.

57. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 57 of the Complaint.

58. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 58 of the Complaint.

59. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 59 of the Complaint.

60. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 60 of the Complaint.

61. Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations of Paragraph 61 as written. To the extent the allegations in Paragraph 61 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself.

62. Paragraph 62 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP admits that the allegations in Paragraph 62 purport to summarize from the FDA-approved Physician Prescribing Information, which document, being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations.

63. BHCP denies the allegations in Paragraph 63 of the Complaint.

64. The allegations contained in Paragraph 64 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the remaining allegations in Paragraph 64 purport to summarize from the DDMAC letter, which document, being in writing, speaks for itself. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced document, BHCP denies those allegations.

65. The allegations contained in Paragraph 65 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the remaining allegations in Paragraph 65 purport to summarize from the DDMAC letter, which document, being in writing, speaks for itself. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced document, BHCP denies those allegations.

66. The allegations contained in Paragraph 66 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the remaining allegations in Paragraph 66 purport to summarize from the DDMAC letter, which document, being in writing, speaks for itself. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced document, BHCP denies those allegations.

67. The allegations contained in Paragraph 67 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the allegations in Paragraph 67 purport to summarize from the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speak for themselves. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced documents, BHCP denies those allegations.

68. The allegations contained in Paragraph 68 are denied as stated. BHCP admits that in December 2009, BHCP received a letter from the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC"). BHCP further admits that the allegations in Paragraph 68 purport to summarize from the DDMAC letter and/or from the Simple Style Program script, which documents, being in writing, speaks for themselves. To the extent Plaintiff's allegations are inconsistent with the actual language or content of the referenced documents, BHCP denies those allegations. Further, BHCP denies making any false representations with regard to Mirena[®].

69. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69 of the Complaint.

70. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 70 of the Complaint.

71. Paragraph 71 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

72. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 72 of the Complaint.

73. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 73 of the Complaint.

74. Paragraph 74 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

75. Paragraph 75 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

FIRST RESPONSE TO “COUNT I NEGLIGENCE (DESIGN DEFECT)”

76. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 75 of the Complaint.

77. BHCP admits that, at certain times not specifically set forth in the Complaint, it sold Mirena[®] in the United States, including in the State of Alabama. BHCP denies the remaining allegations in Paragraph 77.

78. BHCP admits that, at certain times not specifically set forth in the Complaint, it designed, developed, promoted, marketed, distributed, and/or sold Mirena[®]. Due to the vagueness, ambiguity, and potential redundancy of any remaining allegations in Paragraph 78, BHCP is without knowledge or information sufficient to form a belief as to the truth of those allegations.

79. Paragraph 79 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

80. Paragraph 80 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

81. Paragraph 81 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

82. Paragraph 82 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

83. Paragraph 83 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

84. Paragraph 84 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

85. Paragraph 85 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

86. Paragraph 86 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

87. Paragraph 87 (and its subparts) contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

88. Paragraph 88 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

89. Paragraph 89 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

90. Paragraph 90 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

91. Paragraph 91 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

92. Paragraph 92 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP admits that the allegations in Paragraph 92 purport to summarize from the FDA-approved Physician Prescribing Information, which document,

being in writing, speaks for itself. To the extent that Plaintiff's allegations are inconsistent with the actual language or content of the document, BHCP denies those allegations. BHCP denies any additional allegations in Paragraph 92 of the Complaint.

93. Paragraph 93 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

94. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 94 of the Complaint.

FIRST RESPONSE TO "COUNT II FAILURE TO WARN"

95. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 94 of the Complaint.

96. Paragraph 96 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

97. Paragraph 97 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

98. Paragraph 98 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

99. Paragraph 99 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

100. Paragraph 100 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

101. Paragraph 101 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

102. Paragraph 102 contains legal conclusions to which no response is required. To

the extent a response is deemed necessary, BHCP denies the allegations.

103. Paragraph 103 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

104. Paragraph 104 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

105. Paragraph 105 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

106. Paragraph 106 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

107. Paragraph 107 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

108. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 108 of the Complaint.

109. Paragraph 109 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

110. Paragraph 110 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

111. Paragraph 111 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations. BHCP is without knowledge or information sufficient to form a belief as to the truth of the allegation that “Plaintiff did not have the same knowledge as Defendant.”

112. Paragraph 112 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

113. Paragraph 114 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

114. Paragraph 114 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

115. Paragraph 115 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

116. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 116 of the Complaint.

FIRST RESPONSE TO “COUNT III STRICT LIABILITY”

117. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 116 of the Complaint.

118. Paragraph 118 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

119. BHCP admits that, at certain times not specifically set forth in the Complaint, it developed, marketed, distributed, and/or sold Mirena[®]. Due to the vagueness, ambiguity, and potential redundancy of any remaining allegations in Paragraph 119, BHCP is without knowledge or information sufficient to form a belief as to the truth of those allegations.

120. Paragraph 120 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

121. Paragraph 121 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

122. Paragraph 122 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

123. Paragraph 123 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

124. Paragraph 124 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

125. Paragraph 125 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

126. Paragraph 126 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

127. Paragraph 127 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

128. Paragraph 128 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

129. Paragraph 129 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

130. Paragraph 130 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

131. Paragraph 131 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

132. Paragraph 132 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

133. Paragraph 133 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

134. Paragraph 134 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

135. Paragraph 135 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

136. Paragraph 136 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

137. Paragraph 137 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

138. Paragraph 138 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

139. Paragraph 139 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

140. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 140 of the Complaint.

FIRST RESPONSE TO “COUNT IV BREACH OF IMPLIED WARRANTY”

141. This claim was dismissed pursuant to Court Order (ECF Nos. 12-14), therefore no response is required to Paragraphs 141–151. To the extent responses to the allegations in Paragraphs 141–151 are deemed necessary, BHCP denies the allegations.

FIRST RESPONSE TO “COUNT V BREACH OF EXPRESS WARRANTY”

152. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 151 of the Complaint.

153. Paragraph 153 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

154. Paragraph 154 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

155. Paragraph 155 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

156. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 156 of the Complaint.

FIRST RESPONSE TO “COUNT VI NEGLIGENT MISREPRESENTATION”

157. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 156 of the Complaint.

158. Paragraph 158 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

159. Paragraph 159 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

160. Paragraph 160 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

161. Paragraph 161 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

162. Paragraph 162 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

163. Paragraph 163 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

164. Paragraph 164 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

165. Paragraph 165 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

166. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 166 of the Complaint.

FIRST RESPONSE TO “COUNT VII FRAUDULENT MISREPRESENTATION”

167. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 166 of the Complaint.

168. Paragraph 168 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

169. Paragraph 169 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

170. Paragraph 170 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

171. Paragraph 171 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

172. Paragraph 172 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

173. Paragraph 173 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

174. Paragraph 174 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

175. Paragraph 175 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

176. Paragraph 176 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

177. Paragraph 177 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

178. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 178 of the Complaint.

FIRST RESPONSE TO COUNT VIII
“FRAUD BY SUPPRESSION AND CONCEALMENT”

179. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 178 of the Complaint.

180. Paragraph 180 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

181. Paragraph 181 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

182. Paragraph 182 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

183. Paragraph 183 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

184. Paragraph 184 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

185. Paragraph 185 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

186. Paragraph 186 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

187. Paragraph 187 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

188. Paragraph 188 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

189. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 189 of the Complaint.

FIRST RESPONSE TO “REQUEST FOR PUNITIVE DAMAGES”

190. This paragraph requires no response, and BHCP incorporates herein all of its responses to Paragraphs 1 through 189 of the Complaint.

191. Paragraph 191 (and its subparts) of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

192. Paragraph 192 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

193. Paragraph 193 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

194. Paragraph 194 of the Complaint contains legal conclusions to which no response is required. To the extent a response is deemed necessary, BHCP denies the allegations.

195. BHCP denies Plaintiff is entitled to the relief sought in Paragraph 195 of the Complaint. BHCP also denies Plaintiff is entitled to the relief sought in the unnumbered “Wherefore” paragraph (and its subparts) immediately following Paragraph 195.

AFFIRMATIVE/SEPARATE DEFENSES

Discovery and investigation may reveal that one or more of the following additional defenses should be available to Defendant. Bayer HealthCare Pharmaceuticals Inc. accordingly reserves the right to assert these separate and additional defenses. Upon completion of discovery, if the facts warrant, Bayer HealthCare Pharmaceuticals Inc. may withdraw any of these additional defenses as may be appropriate. Bayer HealthCare Pharmaceuticals Inc. further reserves the right to amend its Answer and defenses to assert additional defenses and other claims, as discovery proceeds. Further answering, and by way of additional defense, Bayer HealthCare Pharmaceuticals Inc. states as follows:

FIRST. The Complaint and each claim contained therein fails to state a claim upon which relief can be granted.

SECOND. The claims asserted in the Complaint are barred, in whole or in part, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

THIRD. The claims asserted in the Complaint are preempted by federal law, including (without limitation) the federal Food, Drug, and Cosmetic Act.

FOURTH. Plaintiff's claims are barred, in whole or in part, by the learned intermediary doctrine because adequate warnings were given to learned intermediaries.

FIFTH. The claims asserted in the Complaint are barred, in whole or in part, by Restatement (Second) of Torts § 402A, Comment k, and Restatement (Third) of Torts: Products Liability § 6.

SIXTH. Plaintiff knowingly and voluntarily assumed any and all risks associated with the matters alleged in the Complaint. Pursuant to the doctrines of assumption of the risk and informed consent, this conduct bars in whole or in part the damages Plaintiff seeks to recover.

SEVENTH. Plaintiff's claims are barred because the risks, if any, associated with the use of Mirena are outweighed by its utility.

EIGHTH. Plaintiff's claims are barred, reduced, and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

NINTH. If Plaintiff has sustained any injuries or damages, such were the result of intervening or superseding events, factors, occurrences, or conditions, which were in no way caused by BHCP and for which BHCP is not liable.

TENTH. Plaintiff may not recover from BHCP because the methods, standards, or techniques of designing, manufacturing, and labeling of Mirena[®] complied with and were in conformity with the generally recognized state of the art at the time the product was designed, manufactured, and labeled.

ELEVENTH. Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitations and of repose.

TWELFTH. Plaintiff's claims are barred, in whole or in part, by doctrines of laches, waiver, unclean hands, estoppel, and/or ratification.

THIRTEENTH. Plaintiff's warranty-based claims are barred by Plaintiff's failure to give proper or timely notice of any alleged defect or breach of warranty.

FOURTEENTH. To the extent that Plaintiff's claims relate to BHCP's advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the Constitution of the State of Alabama or that of any other state whose laws may apply, such claims are barred.

FIFTEENTH. Plaintiff's claims are barred, in whole or in part, by Plaintiff's failure to mitigate any damages allegedly sustained.

SIXTEENTH. Plaintiff's damages, if any, were the direct result of Plaintiff's pre-existing medical conditions and/or occurred by operation of nature or as a result of circumstances over which BHCP had and continues to have no control.

SEVENTEENTH. Any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already or will in the future, with reasonable certainty, indemnify Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source such as insurance, social security, workers' compensation, or employee benefit program.

EIGHTEENTH. Plaintiff's injuries and damages, if any, are barred in whole or in part by the actions, omissions, and/or conduct of third parties over whom BHCP had no control or authority and, thus, any recovery should be reduced or barred by such parties' proportionate fault.

NINETEENTH. Plaintiff's claims are barred and/or reduced by Plaintiff's contributory or comparative negligence and Plaintiff's contributory or comparative fault.

TWENTIETH. Plaintiff's claims are barred, in whole or in part, by the alteration, modification, or misuse by Plaintiff or third parties of the Mirena[®] administered to Plaintiff.

TWENTY-FIRST. Plaintiff's claims for punitive or exemplary damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of Alabama or that of any other state whose laws may apply. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional,

facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it fails to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on harms to third parties, out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) unconstitutionally may permit recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to BHCP; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages award; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; (8) would unconstitutionally impose a penalty, criminal in nature, without according to BHCP the same procedural protections that are accorded to criminal defendants under the constitutions of the United States, Alabama, and any other state whose laws may apply; and (9) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996); *State Farm Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

TWENTY-SECOND. Plaintiff's warranty-based claims are barred because Plaintiff was not in privity with BHCP, and are further barred and/or limited by any and all express conditions or disclaimers given by BHCP, and by Plaintiff's lack of reliance upon such warranties.

TWENTY-THIRD. If Plaintiff used Mirena[®], she used it after learning of its alleged risks.

TWENTY-FOURTH. To the extent that Plaintiff is alleging fraud or similar conduct, Plaintiff has failed to plead fraud with sufficient particularity.

TWENTY-FIFTH. BHCP liability, if any, will not result from its conduct but is solely the result of an obligation imposed by law, and thus BHCP is entitled to complete indemnity, express or implied, by other parties.

TWENTY-SIXTH. Plaintiff's injuries and damages, if any, were due to Plaintiff's preexisting condition or idiosyncratic reaction to Mirena[®], for which BHCP cannot be held responsible.

TWENTY-SEVENTH. Should BHCP be held liable to Plaintiff, which liability is specifically denied, BHCP would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasor(s) for the same injuries alleged in Plaintiff's complaint.

TWENTY-EIGHTH. Venue may be improper in this action.

TWENTY-NINTH. BHCP denies it is guilty of conduct for which punitive damages could or should be awarded, and denies that Plaintiff have produced clear and convincing evidence sufficient to support or sustain the imposition of punitive damages against BHCP.

THIRTIETH. Plaintiff's claims may be barred in whole or in part by the doctrine of spoliation of evidence.

THIRTY-FIRST. Plaintiff's claims are preempted by the Supremacy Clause.

THIRTY-SECOND. The product at issue was manufactured and labeled in accordance and compliance with FDA guidelines.

THIRTY-THIRD. Plaintiff's claims are barred because the product at issue was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

THIRTY-FOURTH. To the extent Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate BHCP's rights under the United States Constitution.

THIRTY-FIFTH. BHCP is entitled to, and claims the benefit of, all defenses and presumptions set forth or arising from any rule of law or statute in Alabama and any other state in which the cause of action arose or any other law or statute that may be applicable.

THIRTY-SIXTH. The Complaint is defective in that Plaintiff has failed to join necessary or indispensable parties.

THIRTY-SEVENTH. BHCP hereby raises, asserts, and preserves its right to invoke the doctrine of *forum non conveniens*.

THIRTY-EIGHTH. No action or inaction by BHCP was the proximate, producing, or substantial contributing cause of Plaintiff's alleged injuries and/or damages.

THIRTY-NINTH. Plaintiff lacks standing to pursue their claims and/or seek the requested relief.

DEMAND FOR BIFURCATED TRIAL

If Plaintiff is permitted to proceed to trial upon any claims for punitive or exemplary damages, such claims, if any, should be bifurcated from the remaining issues.

DEMAND FOR JURY TRIAL

BHCP specifically requests and demands a trial by jury on all facts and issues in this action, made up of the maximum allowable number of jurors.

WHEREFORE, Bayer HealthCare Pharmaceuticals Inc. denies any and all liability with regard to Plaintiff's claims, and respectfully requests that Plaintiff's claims against it be dismissed with prejudice and that Bayer HealthCare Pharmaceuticals Inc. be awarded such general, further relief as justice may require.

Dated: April 11, 2014

Respectfully Submitted,

By: /s/ F.M. Haston, III
F.M. Haston, III
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*Attorney for Defendant Bayer
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CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2014, a copy of the foregoing was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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